Study: Primary Care Intervention for Sepsis Survivors

A primary care intervention for sepsis survivors, designed to improve mental health-related quality of life, did not improve mental health outcomes compared to usual care. The trial results are published in the 28 June issue of *JAMA*.

Jochen Gensichen, MD, MSc, MPH, (pictured left), Professor and Chair at the Institute for General Practice & Family Medicine, Friedrich-Schiller University and Jena University Hospital, Jena, Germany, the trial’s Principal Investigator, told *ICU Management & Practice* in an email that in Germany primary sepsis aftercare seems to be better than expected. He added: “Changes for the better may need more intense interventions and may focus on more specific mental health conditions such as depression and post-traumatic stress in order to to improve the mental health-related quality of life.”

The unblinded randomised controlled trial (*Sepsis survivors Monitoring and coordination in Outpatient Health care (SMOOTH)*) assessed whether a primary care-based intervention made a difference to patients’ mental health-related quality of life. The trial involved 291 sepsis and septic shock survivors patients enrolled from 9 ICUs between February 2011 and December 2013, who were assigned either to usual care (143 patients) or a 12-month intervention (148 patients) that included usual care (periodic contact, referral to specialists, medicine prescriptions or other treatment) as well as training in evidence-based care for the primary care doctor and the patient, case management by nurses who were trained in an 8-hour workshop, including information on behavioural activation of patients that included goal setting, and clinical decision support for primary care doctors by consulting physicians.

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The intervention group had a 60 minute face-to-face session with the case manager about sepsis sequelae, followed by monthly phone calls and 3-monthly phone calls for the last 6 months. The nurse case managers monitored symptoms with screening tools and also how patients self-managed physical activity and goals. Results were reported to consulting physicians who provided decision support using a structured written report.

**Results**

- Mean age: 61.6 years
- Male: 66.2%
- Median ICU length of stay: 26 days
- Required mechanical ventilation in ICU: 84.4%

**Primary Outcomes**

At 6 months and 12 months 75 percent and 69 percent of patients completed the follow-up. There was no significant difference in change of scores on the Mental Component Summary (MCS) of the 36-Item Short-Form Health Survey (SF-36) that measured mental health-related quality of life. In the intervention group the mean score change was 3.79 points, in the control group 1.64 points. A change of 5 points of more is considered to be clinically meaningful. Mental health-related quality of life scores at baseline were close to that of the normal population.

**Secondary outcomes**

31 secondary outcomes were measured. The intervention group showed better physical functioning, less physical disability and fewer activities of daily living impairments at 6 months as well as fewer sleep problems at 12 months compared to the control group. The researchers suggest that physical functioning was substantially lower than in the German population and lower than in comparative studies, and therefore patients may have been more sensitive to the intervention’s focus on motivation to be physically active. Prof. Genichen commented that what worked here was teaching both the primary care physicians and the patient to better understand sepsis and its sequelae. “In addition, regular case management by a tenacious nurse with goal-setting and basic behavioural activation may have motivated the patient to realise physical activity”, he said.

**Next Steps**

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Follow up at 24 month post discharge from the ICU is planned. Prof. Gensichen said that they are just starting to analyse this data and looking forward to interesting results.

“Further research is needed to determine if modified approaches to primary care management may be more effective”, the researchers conclude. They suggest that future interventions may address specific postsepsis sequelae.

Genichsen told ICU Management & Practice that there may be a role for common guidelines for ICU and primary care since doctors in both settings are working to help the same patient. He suggested that this kind of cross-sectional guideline may address long-term sequelae such as functional disability, cognitive impairment and psychiatric morbidity.

In an accompanying editorial Shannon L. Goddard, MD and Neill K.J. Adhikari, MDCM, MSc, from the University of Toronto, Canada write: “After discharge from the ICU, astute primary care clinicians, and increasingly patients and their caregivers, will need to be aware of the range of clinical problems encountered by ICU survivors and the help available from specialist physicians and rehabilitation programs. Pending results of additional interventional trials, patients and their caregivers should continue to access these existing services.”

Source: JAMA; interview
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Published on: Tue, 28 Jun 2016